NOV 2 9 2001

Immuno concepts

K013432

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* 510(k) SUMMARY*

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Date Prepared: November 8, 2001
Contact Person: Eric S. Hoy, Ph.D., SI(ASCP)
Name of Device:

- **Trade Name** - IgG Anti-nDNA Fluorescent Test System
- **Common Name** - IgG Anti-nDNA Fluorescent Test System
- **Classification Name** - Anti-DNA Indirect Immunofluorescent Solid Phase (21 CFR 866.5100)

Legally marketed device with which this device has been shown to be equivalent:

"Crithidia lucilliae DS DNA Kit (Diagnostic Use)" distributed by The Binding Site, Ltd., Los Angeles, CA 90064 (K930987, 8/10/93).

Description:

This is an indirect fluorescent antibody test for screening and semi-quantitative detection of IgG anti-nDNA antibody in human serum.

Intended Use:

This is an indirect fluorescent antibody test for screening and semi-quantitative detection of IgG anti-nDNA antibody in human serum. This test system is to be used as an aid in the diagnosis of systemic lupus erythematosus.

Summary of Technological Characteristics Compared to the Predicate Device:

Technologically, this device is similar to the predicate device with the following exceptions:

1. The substrate slide wells consist of concentric circles which decrease potential cross contamination of patient sera.

2. The slides include three additional wells designated positive (+), negative (-), and phosphate buffered saline (PBS) to insure proper performance of controls on slides.

3. Unlike the predicate device and other similar kits, the Immuno Concepts slides are not blotted after each washing step.

Description of Laboratory Data That Indicate Substantial Equivalence:

The Immuno Concepts IgG Anti-nDNA Fluorescent Test System was compared to the "Crithidia lucilliae DS DNA Kit (Diagnostic Use)" distributed by The Binding Site, Ltd., Los Angeles, CA 90064 (K930987, 8/10/93). The population studied consisted of 121 samples which were submitted to clinical laboratories for anti-nDNA testing, 100 blood donors, and 2 WHO standards that are known to contain ant-nDNA antibodies. All samples were tested in parallel on the predicate device and the subject device. Based on this comparison, the following data were obtained:

		Predicate IgG anti-nDNA Test	
		Positive	Negative
Immuno Concepts IgG anti-nDNA	**Positive**	28	0
	Negative	2	193

These data yield the following statistics: relative sensitivity, 93.3%; relative specificity, 100%; positive predictive value, 100%; negative predictive value, 99.0%; and overall agreement, 99.1%

One of the two "false negative" samples was negative for antinuclear antibodies by indirect immunofluorescence using HEp-2 cells, and would not have met the screening criteria for anti-nDNA testing in most clinical laboratories.

To determine intra-assay reproducibility, a single anti-nDNA positive serum was tested in 30 replicates by a single technologist in a single run. The median and mode values for these data were 1:160, with a Geometric Coefficient of Variation of 0.78%. Inter-assay variability was determined by examining the titer values for a single anti-nDNA positive serum as it was run in fifteen different lots of kits. The median and mode values for these data were also 1:160, with a Geometric Coefficient of Variation of 0.82%. In both the inter-assay and intra-assay tests, all titer values fell within plus or minus one dilution of the median.

In accordance with 21 CFR 807.92(b)(3), we conclude from these data that the present device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Eric S. Hoy, Ph.D., SI(ASCP)
Chief, Scientific Officer
Immuno Concepts Incorporated
9779 "D" Business Park Drive
Sacramento, CA 95827

Re: k013432
Trade/Device Name: IgG Anti-nDNA Fluorescent Test System
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: KTL
Dated: October 1, 2001
Received: October 16, 2001

Dear Dr. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K013432

Device Name: IgG Anti-nDNA Fluorescent Test System

Indications for use:

This is an indirect fluorescent antibody test for screening and semi-quantitative detection of IgG anti-nDNA antibody in human serum. This test system is to be used as an aid in the diagnosis of systemic lupus erythematosus.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan S. Altuie

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013432

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)